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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,806	07/16/2001	Wallace G. Buchholz	FWS-3679	3551

7590

04/25/2002

Carla Mattix
Division of General Law, Office of the Solicitor
U.S. Department of the Interior
1849 C Street NW, MS 6531
Washington, DC 20240

EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 04/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,806

Applicant(s)

BUCHHOLZ ET AL.

Examiner

Frank Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, claims 1-9 in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Information Disclosure Statement

2. The listing of references in the specification (see pages 8 and 9) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Sequence Rules Compliance

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

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Direct the reply to the undersigned.

Specification

4. The disclosure is objected to because of the following informalities: (1) There are two nucleic acid sequences in page 6 of the specification. However, there is no SEQ ID NO; (2) There are several nucleic acid sequences in Figure 1. However, there is no description for these sequences in BRIEF DESCRIPTION OF THE DRAWING (page 5). Furthermore, these sequences were not in the specification and no SEQ ID No is related to each of these sequences; and (3) there is no description of item 38 of Figure 3 in the specification.

Appropriate correction is required.

Claim Objections

5. Claim 9 is objected to because of the following informality: there is no period in the end of the claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Warburton *et al.*, (Nucleic Acids Res., 20, 6033-6042, 1992) in light of Cocuzza *et al.*, (US Patent No. 5, 484,701, published on January 16, 1996).

Warburton *et al.*, teach PCR amplification of tandemly repeated DNA. By using a novel application of the polymerase chain reaction (repPCR), they amplified a representative sampling of multiple repetitive units from human chromosomes 17 and X and directly sequenced repPCR amplified alpha satellites in the presence of ddNTP as recited in claims 1 and 2 (for examples, see abstract in page 6033, pages 6034 and 6035, and Figures 1 and 2). Note that: (1) a repPCR

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amplified alpha satellite with multiple repetitive units such as a 1.9 kb fragment containing 16 mer repeat units (see Figure 1 and page 6035) was considered as a DNA template as recited in claims 1 and 7; (2) the multiple repetitive units such as 16 mer repeat units (see above) was considered as a motif sequence comprising a sequence with at least one unique nucleotide base as recited in claim 8; (3) sequencing ladders in Figure 3 could be considered as DNA fragments comprising a number of copies of the motif sequence as recited in claim 9; and (4) DNA fragments in the sequencing gel could be considered to lack secondary structure as recited in claim 3 since these DNA fragments was denatured by a high concentration of urea (6-8 M) during the process of electrophoresis (for an example, see column 12 in US Patent No. 5, 484,701).

Therefore, Warburton *et al.*, teach all limitations recited in claims 1-3 and 7-9.

9. Claims 1-9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Xu *et al.*, (US Patent No. 6,197,509 B1, 102(e) date: May 13, 1999) in light of Cocuzza *et al.*, (US Patent No. 5, 484,701, published on January 16, 1996).

Xu *et al.*, teach a method of analyzing DNA using contiguous repeats. As shown in Example 1, a cosmid containing human inducible nitric oxide synthase gene coding region and its promoter region was shot-gun cloned with Pst I and Hind III restriction enzymes into pBluescript SK vector. Subclones were then sequenced using an ABI automatic sequencer with M13 universal and reverse primers. One of the Pst I subclones was shown to contain 11 perfect

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contiguous pentanucleotide repeats (CCTTT/GGAAA) (microsatellite repeat) (see column 3 and Figures 1A and 1B). Note that: (1) the Pst I subclone containing 11 perfect contiguous pentanucleotide repeats was considered as a DNA template as recited in claims 1 and 4-7; (2) pentanucleotide repeat (CCTTT/GGAAA) was considered as a motif sequence comprising a sequence with at least one unique nucleotide base as recited in claim 8; (3) although Xu et al., did not directly show to perform a dideoxy sequencing reaction using the DNA template in the presence of one of dideoxy nucleotide terminator and run a sequencing gel as recited in claims 1, 2, and 9, in the absence of convincing evidence to the contrary, these limitations were considered to be inherent to the reference taught by Xu et al., since it was well known that a DNA sequencing reaction was performed in the presence of one or more dideoxy nucleotide terminators and could generate a series of different sizes of DNA fragments (here DNA fragments comprising a number of copies of the motif sequence as recited in claim 9) (for an example of sequencing ladders, see Warburton *et al.*); and (4) DNA fragments in the sequencing gel could be considered to lack secondary structure as recited in claim 3 since these DNA fragments was denatured by a high concentration of urea (6-8 M) during the process of electrophoresis (for an example, see column 12 in US Patent No. 5, 484,701).

Conclusion

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

A handwritten signature in black ink, appearing to read 'Frank Lu', is written above the printed name.

Frank Lu
April 21, 2002